

REMARKS

The Office Action of November 5, 2003, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

Responsive to the Examiner's objections to the drawings, submitted herewith are proposed drawing changes and a corrected drawing for FIG. 1. As noted by the Examiner, reference number 54 in FIG. 1 has been deleted since it is not mentioned in the specification. With respect to reference number 102, the Examiner's attention is kindly directed to FIG. 2, wherein reference number 102 designates a partition in the illustrated tray. Accordingly, in view of the proposed changes submitted herewith, Applicant respectfully contends that the Examiner's objections to the drawings have been obviated. Formal drawings incorporated the proposed changes are also enclosed.

In the above Office Action, claims 1, 12, 20, 21, 30 and 35 were rejected under 35 U.S.C. § 102(e) over *Lindsay et al.*, while claims 2, 8-11, 13, 25-29, and 32-34 were rejected under 35 U.S.C. § 103 over *Lindsay et al.* in view of *Fukasawa*. These rejections are respectfully traversed.

The Examiner is kindly requested to note that the inventorship of *Lindsay et al.* and the inventorship of the present application both include Erin J. Lindsay, but that the inventorship of *Lindsay et al.* is different from the inventorship of the present application. Specifically, Ronald J. Leonard, one of the co-inventors in *Lindsay et al.*, is not an inventor in the present application and therefore does not appear on the Declaration for the present invention. The presently named inventor, Erin J. Lindsay, can unequivocally state she conceived or invented the subject matter disclosed in

Lindsay et al. upon which the Examiner is relying, as set forth in the attached unexecuted Declaration, a signed and dated copy to be submitted shortly.

Hence, in accordance with MPEP § 716.10, Applicant has successfully attributed *Lindsay et al.* to the Applicant, rendering *Lindsay et al.* no longer applicable to the presently claimed invention. Accordingly, withdrawal of the above rejections over *Lindsay et al.* are respectfully requested.

Also in the above Office Action, claims 2-11 and 29-31 were rejected under 35 U.S.C. § 101 as claiming the same invention as claims 1-13 of prior U.S. Patent No. 6,306,346 and claims 1, 13-18, 20 and 22-28 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,306,346.

Responsive to the double patenting rejection, Applicant respectfully notes that independent claim 1 of granted U.S. Patent No. 6,306,346 recites the limitation in clause (d) of "at least one tray releasably attached to ...". Since this limitation was not found in claim 1 of the present application, or in the claims depending directly therefrom, Applicant contends that a double patenting rejection is not proper. Nevertheless, in view of the cancellation of claims 1-11, 30 and 31, and the amendment of claim 29, this rejection is now moot.

A Terminal Disclaimer and the requisite Terminal Disclaimer fee is submitted concurrently herewith. Accordingly, Applicant respectfully submits that the obviousness-type double patenting rejections have been obviated.

The only remaining rejection in the Office Action rejects claims 1, 4, 12, 16, 18, 20, 29, 30 and 32-35 under 35 U.S.C. § 103(a) as being unpatentable over U.S.

Patent No. 5,800,721 to *McBride* in view of *Fukasawa*. For at least the reasons set forth below, Applicant respectfully traverses these rejections.

Independent claim 12 is directed to a pack assembly for use in an extracorporeal blood circuit. The pack assembly comprises a carrier adapted to mount a blood reservoir and a blood oxygenator, said carrier including a mounting element, and said carrier being adapted for mounting on a support; a blood reservoir releasably attached to the mounting element; and a blood oxygenator releasably attached to the mounting element.

As a result of this unique construction, and as specifically recited in claim 12, the carrier is able to independently and separately mount the blood reservoir and the blood oxygenator such that one of the blood reservoir and the blood oxygenator may be removed from the carrier without removing the other. The ability to provide independent and separate mounting of these elements provides a significant advantage to the practitioner and, among other advantages, allows for faster and more reliable replacement of a malfunctioning part during surgery because it eliminates the necessity of replacing both components, as described in the Paragraph [0038] of the specification.

The primary reference relied upon by the Examiner, *McBride*, discloses a reservoir 10 including a housing 12 having a lower portion 14 with a side wall 16 and a lower wall 18 including a fluid outlet 20. The lower wall 18 includes wall part 18a and wall part 18b which leads into a basin 50, as shown in Figure 2. The "basin 50" asserted by the Examiner to suggest the carrier or support member of the present invention merely defines a portion of the *interior* structure of the reservoir 10.

Applicant respectfully contends that the basin 50 does not define "a carrier adapted

to mount a blood reservoir and a blood oxygenator," as recited in claim 12, since it is not possible to mount a blood reservoir on the basin 50, which in itself defines part of the interior of the reservoir 10.

Further, the reservoir of *McBride* has a lower hanging bracket 44 with a pair of depending hook-shaped portions 46. The bracket 44 and hooks 46 allow attachment of an oxygenator/heat exchanger to the reservoir 10 for "convenient fluid flow interface therewith." Col. 6, lines 54-63. Even if *McBride* were combined with the teachings of *Fukasawa* as alleged by the Examiner and used in an extracorporeal circuit, because there is a fluid flow interface during use, the reservoir and the oxygenator of *McBride* would function together as a unit and it would not be feasible to remove one or the other without a collapse of the extracorporeal blood circuit.

In contrast, the invention of claim 12 avoids a direct fluid flow interface between the reservoir and the oxygenator. That is, the carrier of claim 12 is adapted to "independently and separately mount said blood reservoir and said blood oxygenator such that when used in an extracorporeal blood circuit one of said blood reservoir and said blood oxygenator may be removed from said carrier without removing another of said blood reservoir and said blood oxygenator."

Accordingly, Applicant respectfully submits that independent claim 12 and the claims depending therefrom are now in condition for allowance, along with method claims 35-37 and new independent claim 38 and the claims depending therefrom.

Method claim 32 is directed to providing a pack assembly including a blood reservoir, a blood oxygenator, and at least one tray including a plurality of tubing assemblies. The prior art upon which the Examiner relies fails to disclose or suggest the use of a tray for tubing and allowing the selective deployment of tubing from the

tray. Accordingly, Applicant contends claims 32-35 are patentable over the cited prior art.

CONCLUSIONS

In view of the above submission, Applicant respectfully submits that pending claims 12-29 and 32-43 are now in condition for allowance.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application, the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

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